10/23/03

K032698

Coapt

11 510(k) SUMMARY

11.0 510(k) Summary

Coapt Systems is providing a summary of the safety and effectiveness information available for the ENDOTINE Midface™-ST 4.5 Device. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

SPONSOR/APPLICANT NAME AND ADDRESS

Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA
Telephone: (650) 461-7600
Facsimile: (650) 213-9336

CONTACT INFORMATION

Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
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DATE OF PREPARATION OF 510(K) SUMMARY

August 29, 2003

DEVICE TRADE OR PROPRIETARY NAME

ENDOTINE Midface™-ST 4.5 Device

DEVICE COMMON OR CLASSIFICATION NAME

Classification Name: Absorbable Poly (glycolide/L-lactide) Surgical Suture
Regulation Number: 878.4493
Class: II
Product Code: GAM

IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Name of Manufacturer	510(k) or PMA Number
ENDOTINE Forehead™ Device	Coapt Systems, Inc	K023992/K014153
PDS II Suture	Ethicon, Inc.	N18331
Lactosorb® Panels	Walter Lorenz Surgical	K974309

DEVICE DESCRIPTION

The ENDOTINE Midface™-ST 4.5 consists of insertion tools and bioabsorbable implants. The device implant consist of two components: (1) a fixation platform attached to an anchoring leash, and (2) an anchoring tack. This device along with its insertion tools are supplied sterile for single use only.

INTENDED USE STATEMENT

The ENDOTINE Midface™-ST 4.5 is indicated for use in subperiosteal midface suspension surgery to fixate the cheek subdermis in an elevated position.

SUBSTANTIAL EQUIVLANCE COMPARISON

1. Indications Summary

The "Indication Statement" for the ENDOTINE Midface™-ST 4.5 is substantiated by the results of the performance evaluations and comparison testing to the PDS II Suture predicate device. The intended use statement for the ENDOTINE Midface™-ST 4.5 is more specific than that of the predicate device, but both devices are approved for use in soft tissue. In addition, the selected predicate device is routinely used in the midface lift procedure. The differences between the ENDOTINE Midface™-ST 4.5 and the predicate device do not affect the safety and effectiveness of the ENDOTINE Midface™-ST 4.5. An appropriate and complete testing program supports the ENDOTINE Midface™-ST 4.5 is suitable to perform and operate as clinically intended.

2. Technological Characteristics Summary

The ENDOTINE Midface™-ST 4.5 is substantially equivalent in design, materials and fundamental scientific technology to the ENDOTINE Forehead and Lactosorb Panel predicate devices. Further, the technological characteristics of the ENDOTINE Midface-ST 4.5 are similar to many absorbable, implantable general, orthopedic and plastic surgery devices legally distributed by other manufacturers. Any differences between the ENDOTINE Midface™-ST 4.5 and the predicate devices are minor and do not raise issues regarding safety or effectiveness. This statement is substantiated by a history of

clinical use with the ENDOTINE Forehead device, and an established safety profile of the device material in the midface (bone and tissue).

3. Performance Summary

The ENDOTINE Midface-ST 4.5 Device is safe and appropriate for the intended use due to the following:

- Its similarity to the predicate devices.
- A design pathway that included extensive cadaver modeling and evaluations which exceeded user specifications and USP Standards for absorbable surgical sutures.
- Feedback and user observation from several leading surgeons.

The ENDOTINE Midface™-ST 4.5 performance data meet the applicable standards and fulfill the device requirements as defined in the user specifications.

SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the design, materials, function, intended use, and performance evaluations discussed herein, Coapt Sysems believes the ENDOTINE Midface™-ST 4.5 is substantially equivalent to the predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. No new issues of safety or effectiveness were raised for the ENDOTINE Midface™-ST 4.5 Device. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Ms. Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, California 94303

Re: K032698
Trade/Device Name: ENDOTINE Midface™-ST 4.5
Regulation Number: 21 CFR 878.4493, 888.3040
Regulation Name: Absorbable suture, Bone fixation screw
Regulatory Class: II
Product Code: GAM, HWC
Dated: August 29, 2003
Received: September 2, 2003

Dear Ms. DonDiego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032698

4 STATEMENT OF INDICATIONS FOR USE

510(k) Number:	Not yet assigned
Device Name:	ENDOTINE Midface™-ST 4.5
Indications for Use:	The ENDOTINE Midface™-ST 4.5 is indicated for use in subperiosteal midface suspension surgery to fixate the cheek subdermis in an elevated position.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ or Over-the-Counter
Per 21 CFR 801.109 Optional Format 1-2-96

for Mark N Milhous

(Division Sign-Off)
Division of General. Restorative
and Neurological Devices

510(k) Number K032698